IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANT: Modell et al. CONFIRM. NO.: 6590

SERIAL NO.: 09/841,325 GROUP NO.: 3737

FILING DATE: April 24, 2001 EXAMINER: Smith, Ruth S.

TITLE: METHOD AND APPARATUS FOR SCANNING A BIOLOGICAL

SAMPLE

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 41.41

Appellants hereby submit this Reply Brief under 37 C.F.R. § 41.41 in response to the Examiner's Answer dated June 22, 2007. Appellants respectfully submit that the Examiner's Answer does not overcome the deficiencies of the Final Office action dated August 24, 2006. Accordingly, Appellants incorporate herein by reference all arguments presented in the first Appeal Brief, filed May 2, 2007. In addition, Appellants submit the following remarks on the new matters and reasoning raised in the Examiner's Answer.

REMARKS

I. The Examiner Relies on Mistaken Interpretations of the Prior Art

Each of the pending independent claims 105 and 152 recites the limitation, "an internal biological sample, ... said sample not surgically exposed". The Examiner fails to show where this limitation allegedly appears in the cited art.

In the June 22, 2007 Examiner's Answer, the Examiner alleges that "Zavislan clearly distinguishes between cervical tissue and internal tissues that are surgically exposed," and further argues that "[i]t is well known in the art that examination of cervical tissue does not require surgical exposure of the tissue."

Appellants respectfully traverse. Examination of cervical tissue using the device of Zavislan clearly would require surgical exposure, as admitted in Zavislan. Zavislan describes a device for examination of the skin. Zavislan does not teach or suggest "an internal biological sample, ... said sample not surgically exposed". Even if one could argue the few lines of Zavislan dealing with "internal tissues" (col. 7, lines 45-47) enables one to use its skin examination device to examine a surgically-exposed cervix (such surgical exposure being necessary, as admitted at lines 45-47 of Zavislan, given the device described therein – a point which will be discussed in more detail below), this would still not teach or suggest scanning "regions of an internal biological sample ... said sample not surgically exposed." [emphasis added] as recited in each of independent claims 105 and 152.

Methods and systems according to the current invention can be used to scan internal tissue that is accessed via a probe – for example, using equipment such as an endoscope, laparoscope, or arthroscope – without the need for surgically exposing the tissue. For example, the specification states at page 11, lines 1-5:

To provide internal analysis, the invention is adapted to work with existing endoscopes, laparoscopes, or arthroscopes. To adapt the invention for diagnostic purposes involving contact with biological tissues, the invention can be provided with a covering that can be disposable to insulate the instrument from contact with biological tissues.

Furthermore, Figure 17 shows an embodiment of the invention positioned within a body cavity (within the female perineum) for scanning of non-surgically exposed regions of cervical tissue.

In contrast, Zavislan briefly refers to scanning of surgically exposed cervical tissue, wherein the cervical tissue is maintained <u>under tension or compression</u> during scanning. For example, Zavislan states, at column 7. lines 38-47:

Each of the above confocal imaging system embodiments provides a mechanism for maintaining an area of skin tissue being confocal imaged under a stressed configuration by tension or compression, thereby minimizing the motion of this area with respect to a confocal imaging head. In the cervix the tissue being imaged is not skin as that term is commonly understood, but represents internal tissue of a patient. Internal tissues, for example which are surgically exposed, may be stabilized using the invention. [emphasis added]

In the June 22, 2007 Examiner's Answer, the Examiner alleges that "Zavislan clearly distinguishes cervical tissue from other internal tissue by use of the recitation of 'internal tissues, for example which are surgically exposed'." However, Zavislan states, at column 7, lines 43-47:

In the cervix the tissue being imaged is not skin as that term is commonly understood, <u>but represents internal tissue</u> of a patient. <u>Internal tissue</u>, for example which are surgically exposed, may be stabilized using the invention. [emphasis added]

Zavislan does not distinguish cervical tissue from surgically exposed internal tissues, but rather *includes* cervical tissue among surgically exposed internal tissues for which the device may be used. Zavislan clearly indicates that cervical tissue "represents internal tissue", and that "surgically exposed" internal tissues "may be stabilized using the invention." The use of the term "for example" at column 7, line 45, cannot be read to support the Examiner's allegation that Zavislan teaches use of its device with non-surgically exposed cervical tissue. Zavislan merely contemplates using his device to stabilize surgically exposed internal tissue, for example, surgically exposed cervical tissue, wherein the cervical tissue is maintained under tension or compression during scanning.

As such, the Examiner's rejection fails to satisfy the requirements of 35 U.S.C. §103, because neither Zavislan nor the additionally cited art, alone or in proper combination, teaches or suggests every element of the invention as claimed.

CONCLUSION

In view of the arguments above, Appellants respectfully submit that claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 are patentable over the cited references. Appellants urge the Board of Patent Appeals and Interferences to reverse all of the Examiner's rejections as to all of the claims, and request allowance of claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 in due course.

Appellant does not believe any fee is required for filing this Reply Brief. Should Appellant's belief be in error, the Commissioner and Director are hereby authorized to charge any fees that may be due to Appellant's undersigned counsel's deposit account number 07-1700, with reference to docket number MDS-009CN.

Respectfully submitted,

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Reg. 140. 55,002

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